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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,406	08/02/2001	Zohar Yakhini	10010313-1 (2003309-0012)	6019
22878	7590	12/27/2004	EXAMINER	
AGILENT TECHNOLOGIES, INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT. P.O. BOX 7599 M/S DL429 LOVELAND, CO 80537-0599			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,406

Applicant(s)

YAKHINI ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Re: Yakhini *et al.*

Date of priority: 08/02/2001

Request for Continued Examination

The request filed on 10-12-04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/921406 is acceptable and a RCE has been established.

Applicants have requested entry of the previous amendment filed August 30, 2004 which replaces all prior versions. This request has been accepted. An action on the RCE follows.

Claims 1-4, and 21-25 are pending.

Claims 5-20 are cancelled.

Claims 2-3, and 21-24 have been withdrawn by applicants

Claims 1, 4, and 25 are currently under consideration.

Drawings

The conditions for accepting color drawings have been satisfied.

Claim Objections

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Claim 25 limits the cancer of claim 4 to "malignant melanoma".

However, the method of claim 4 is already drawn to diagnosing malignant melanoma.

Furthermore, claim 25 is indefinite- see 112, 2nd rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 recites the limitation "the cancer" in reference to claim 4. There is insufficient antecedent basis for this limitation from which claim 25 depends. (i.e. , there is no recitation of the word "cancer" in claim 4.)

Claim 1 is further rejected as vague and indefinite for reciting "invasive ability" as the specification fails to teach an active step for determining an "invasive ability". Further, it is not clear how 3.5% represents the value of the invasive ability. How is the value of 3.5% determined? The ability of tumors cells to invade other tissues is a highly complex process involving multiple steps. However, the claims do not particularly point out nor distinctly claim the steps necessary in assessing the ability of tumor cells to invade. Hence, the method is vague and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 1 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a tumor having “less than about 3.5% invasive ability” has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the “limitation” indicated above. See MPEP 714.02 and 2163.06

Claims 4 and 25 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims are drawn to a method of diagnosing an aggressive form of malignant melanoma comprising providing a genetic sample from a test sample of a tumor, determining expression of Wnt5a, wherein increased expression of Wnt5a in the test sample compared to the expression of Wnt5a in a tumor that has no detectable vasculogenic mimicry indicates that the tumor is aggressive. It does not appear that the specification contemplates nor suggests this particular comparison step in conjunction with determining or discrimination between an aggressive form of melanoma. For example, in reference to diagnosing and identifying forms of cancer, the specification teaches (page 12) that:

Once a genetic sample has been obtained, it can be analyzed for the presence or absence of particular marker genes. The analysis may be performed using any techniques known in the art including, but not limited to, sequencing, PCR, RT-PCR, quantitative PCR, restriction fragment length polymorphism, hybridization techniques, Northern blot, microarray technology, DNA microarray technology, etc. In determining the expression level of a marker gene or genes in a genetic sample, the level of expression may be normalized by comparison to the expression of another gene such as a well-known, well-characterized gene or a housekeeping gene.

Applicants appear to be claiming a broad method of diagnosing an aggressive “form” of clinical melanoma via the expression of wnt5a wherein the comparison step involves one

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parameter: the presence or absence of vascular mimicry. However, there does not appear to be a nexus for the comparison of wnt5a expression in a tumor versus wnt5a expression in a tumor that has no vasculogenic mimicry because the specification only appears to contemplate comparison to the expression of another gene such as a housekeeping gene. Further, vasculogenic mimicry appears to be a particular phenotype (Maniotis *et al.*, IDS), but it's not clear in the disclosure what parameters distinguish tumors with vasculogenic mimicry versus tumors without vasculogenic mimicry. Thus, it appears that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Hence, the instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER